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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,575	03/31/2004	Ilya Malyarov	2008P26174 US	4329

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EXAMINER	
WRIGHT, PATRICIA KATHRYN	
ART UNIT	**PAPER NUMBER**
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,575	MALYAROV ET AL.	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed June 11, 2008 in which claim 1 was amended and claim 18 added. The amendments have been thoroughly reviewed and entered. Any rejection/objection not repeated herein has been withdrawn.

Claims 1-18 are pending.

Election/Restrictions

2. Newly submitted claim 18 is directed to an invention that is distinct from the invention originally claimed for the following reasons. New claim 18 requires a read station be located between a detector and a transport device. This is not required in claims 1-17. The read station of claim 18 includes the negative limitation of not accepting any other vessels at said entry position while a received vessel is in the read station. This is also not required in claims 1-17. The inventions listed in this action are distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because of the following: the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries), the prior art applicable to one invention would not likely be applicable to another invention, and the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17 are again rejected under 35 U.S.C. 102(b) as being anticipated by Babson et al. (US Patent no. 5,885,529).

Babson *et al* teach an analyte detection station for an automated immunoassay analyzer, comprising a wash station 214, a reaction reading station which includes an oval luminometer chain 215a that rotates between an entry position (at the wash station 214) and a read position at a detector (photomultipler tube (PMT)); (col. 8, line 31; Figs. 2a, 2b).

The detector (photomultiplier tube 216a) is coupled with the read station for detecting radiant energy.

The analyzer of Babson also includes a transport device 213b (side chain) for transporting a plurality of vessels 27 through a defined path. The transport device 213b rotates between wash station 214 (near the entry position of the read station) and a

pipette station 204. The wash station 214 includes an angled, splined chuck surrounded by a receptacle and a tube elevating device (as shown in FIGS. 8A and 8E). Reaction tubes are elevated onto this chuck and then rotated about their longitudinal (vertical) axes at high speed. Thus, the tubes are removed from transport device of Babson into the wash station 214 to be washed. After washing the beads at the wash station 214, the reaction tubes are lowered by the chuck. The transport device 213b receives the vessels from the wash station and transports the reaction tubes to reaction pipetting station 204 along a path defined by the side chain 213b where more reagent(s) is added, if necessary (see col. 7, line 66 - col. 8, line 39). After reagent addition, the transport device (chain 213b) transfers the reaction from the path (chain 213b) to the wash station where the step of incubation and wash are repeated (see col. 8, lines 21-29) and into the read station (i.e., 215a) at the entry position. Note the "comprising" language of the claims do not preclude the transport device transferring the plurality of vessels from the defined path of the transport device and into the read station via the wash station 214.

The read station of Babson *et al* has a shield (i.e., shutter; not shown but disclosed at col. 9, lines 27-30) for shielding external radiant energy when at the read position. Thus, only radiant energy from one of the plurality of vessels is detected by the detector.

Regarding claims 2 thru 4, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., chemiluminescence, fluorescence, phosphorescence, etc.,) fails to differentiate the

claimed apparatus from a prior art apparatus if the prior art apparatus teaches *all the structural limitations* of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). While Babson *et al* do not explicit teach a detector that detects phosphorescence, such a limitation is merely an intended use, which the prior art would inherently be capable of doing. The only distinction between applicants' claims and the prior art is recited functional language. It is incumbent upon Applicants to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re* Ludtke, 169 USOQ 563 (CCPA 1971). Moreover, Babson *et al* explicitly teach fluorescent, radioactive, chemiluminescent detection (col. 1, lines 20-34 and col. 8, lines 40-64).

With respect to claim 6, the Examiner considers the read station oval luminometer chain 215a as "biasing" the test vessel a set distance from the detector when in the read position before the PMT.

With respect to claim 8, the motor of the transport device moves the transferred vessel to a disposal station (col. 8, lines 32-33.)

Regarding claims 10 and 11, the transport device is a continuous belt having teeth (i.e., receptacle vessels) that receive the plurality of vessels. The belt can receive the vessel at a plurality of locations.

With respect to claims 12-16, Babson *et al* teach an attenuation means (rotatable filter wheel) for attenuating light signals. The attenuation means is located between the read station (which includes the transport device 215a) and the detector, and can be set at any three attenuation positions (see col. 9, lines 21-49). The three attenuation

positions include: an unattenuated position where light from the vessel can be read directly by the detector; an attenuated position where light from the vessel can be read by the detector through neutral density filter; and a dark position where no light from the vessel can be read by the detector.

Regarding claim 17, the detection station of Babson *et al* include a means for measuring dark counts (i.e., computer 12). The computer uses these values to calibrate "noise" in the PMT (col. 9, lines 44-49.)

Response to Arguments

5. Applicant's arguments filed June 11, 2008 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 1-17 under 35 U.S.C. 102(b) as being anticipated by Babson et al. (US Patent no. 5,885,529), Applicant concedes that Babson the chain 213b carries vessels from the chain 213' to the wash station 214 and may also carry vessel from the wash station 214 to the pipetting station 204. However, Applicant argues that Babson allegedly does not teach transporting vessel received from the wash station 214 onto the luminometer chain 215a.

The Examiner respectfully disagrees with Applicant's argument. The analyzer of Babson includes a transport device 213b (side chain) for transporting a plurality of vessels 27 through a defined path. That is, the transport device 213b rotates between the wash station 214 (near the entry position of the read station) and a pipette station 204. The wash station 214 includes an angled, splined chuck surrounded by a

receptacle and a tube elevating device (as shown in FIGS. 8A and 8E). When washing is required, the reaction tubes are elevated onto this chuck (i.e., removed from transport device) and washed. After washing, the reaction tubes are lowered by the chuck back onto the transport device 213b, i.e., received from the wash station. The transport device 213b can then return the tube to reaction pipetting station 204 by rotation (see col. 7, line 66 - col. 8, line 39). After reagent addition, the transport device (chain 213b) transfers the reaction tubes from the path (chain 213b) to the wash station where the step of incubation and wash are repeated and into the read station (i.e., 215a) at the entry position. See col. 8, lines 21-29. In other words, the transport device 213b Babson transfers the plurality of vessels from the defined path of the transport device and into the read station via the wash station 214.

Thus, for the reasons delineated above, the rejection of claim 1-17 U.S.C. 102(b) as being anticipated by Babson is maintained.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797